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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/228,866 01/12/99 RUOSLAHTI E P-LJ3430

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EXAMINER

TURNER, S

ART UNIT

PAPER NUMBER

1647

15

DATE MAILED:

11/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/228,866

Applicant(s)

Ruoslahti E

Examiner

Sharon L. Turner, Ph.D.

Group Art Unit

1647



☒ Responsive to communication(s) filed on 7-18-00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 13-41 is/are pending in the application

Of the above, claim(s) 13, 21-23, and 25-27 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 14-20, 24, and 28-41 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 13-41 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1644

Response to Amendment

1. The Art Unit of U.S. Patent application SN 09/228,866 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1647.

Request for Continued Examination

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-18-00 has been entered.

3. The amendment filed 7-18-00 has been entered into the record and has been fully considered. Claims 13-41 are pending.

Election/Restriction

4. As set forth in the Final Action of 2-16-00, newly submitted claims 13, 21-23, and 25-27, are directed to an invention that is independent or distinct from the invention originally claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13, 21-23 and 25-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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5. Applicants request for rejoinder has been considered. However, claims 13, 21-23 and 25-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant affirmed the election in Paper No. 8, filed 11-29-99.

6. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 14-20, 24, and 28-41 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not reflect the hand of man and should be amended to reflect the hand of man, for example to recite, "A synthesized peptide..."

Claim Rejections - 35 USC § 112

9. Claims 14-20, 24 and 28-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for selected small peptides which selectively home, for example as exemplified at p. 37, lines 1-9, including those consisting of SEQ ID Nos:1-3 and 16, does not reasonably provide enablement for selective brain homing of any other peptide sequence. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that demonstration of at least 2-fold greater specific binding is sufficient to establish that a peptide of the invention homes to brain without additional laboratory analysis.

These arguments have been considered but are not fully persuasive as set forth herein. It is noted that the assertion that a peptide has at least 2-fold greater specific binding is sufficient to establish that a peptide homes to brain are limitations which are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

In particular it is noted that selected peptides have been shown to selectively home as defined by exhibiting at least 2-fold greater specific binding in brain than to kidney. However, other than those specific peptides as exemplified in the specification at p. 37, lines 1-9, no other peptides, no large peptides ^{and} ~~an~~ no peptides containing a certain motif have been shown to demonstrate the ability to specifically home. Although a specific test with a defined reference

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organ provides an indication that a peptide may selectively home, the claimed peptides have only been measured with respect to a single organ other than brain (kidney). "Selective homing" indicates that the peptide is more abundant in that organ than any other control organ. As no other organs have been tested, the skilled artisan would have reason to doubt that the peptide selectively homed to brain in the absence of data showing that following administration, the peptides selectively homed to brain over any other control organ. Thus, the scope of enablement is not commensurate with the scope of the claims, in particular with respect to the recited formulas of untested peptide sequences and sequences comprising certain SEQ ID residues. One of skill in the art would be required to perform further undue experimentation to establish that

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the claimed peptides selectively homed to any particular organ in comparison to a second reference organ.

In addition, the data as indicated in Table I, only supports homing of relatively small peptide molecules as capable of mobilizing to the brain. The skilled artisan recognizes the relative selectivity of the blood brain barrier and exclusion therefrom of large molecules from entering the brain via the blood stream, see in particular Kandel et al., Ed., Principles of Neural Science, Elsevier, 1991, p. 1056, column 1, lines 28-46. Thus, the skilled artisan would not expect any peptide molecule *comprising* a particular motif (as is claimed) to be capable of homing to the brain (since the peptides in question include those large in comparison to those capable of traversing the blood brain barrier). With respect to applicants evidence and claims reciting peptides of the SRL and VLR motifs, applicants have only shown two peptides of the SRL motif and a single peptide of the VLR motif which possesses the claimed ability of selectively homing to brain (as exemplified in the specification at p. 37, lines 1-9.) Claimed SEQ ID Nos:6-9 fail to contain a "peptide homing motif" and have not been demonstrated to selectively home to the brain.

The examiner notes that the identified peptides have been isolated through an *in vivo* panning technique which is unpredictable as to those molecules which will be isolated in abundance from any particular reference organ. In addition as the ability to cross the blood brain barrier is unpredictable with respect to the genus of claimed peptides, the isolation of three specific peptide species fails to provide a reasonable expectation that the peptides of the claimed

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genus are capable of obtaining access and selectively homing to brain. In particular it is noted that of the peptides isolated from brain as disclosed in Table I, there are only 5 species of the representative genus encompassing any peptide sequence possible comprising the SRL and VLR motifs which were capable of being recovered from (homing to) the brain. Thus, as the experimental procedures utilized result in the identification of peptide sequences which are unpredictable in nature other than by experimental isolation and testing for any identified reference organ, the skilled artisan is forced to perform further undue experimentation to make and use the claimed invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 15-20 and 28-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted as previously set forth in the scope of enablement rejection that the term, "selectively homes to the brain," is a relative term which lacks distinct metes and bounds whereby the applicant can identify those peptides which are deemed to "selectively home." Thus, applicants claims are indefinite with respect to such recitations. Claims amendments such as that presented for claim 14, including the recitation of "wherein the peptide exhibits ant least two-fold greater specific binding to brain than to kidney" would further prosecution.

Status of Claims

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12. No claims are allowed.

Conclusion

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
November 16, 2000

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud